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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,394	05/16/2001	Naoto Miwa	SCH 1799	2377

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EXAMINER

SHARAREH, SHAHNAM J

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 12/18/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/787,394

Applicant(s)

MIWA ET AL.

Examiner

Shahnam Sharareh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 5/16/2001, 10/24/2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 10-12, 14-16, 18-20 and 25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 13, 17, 21-24 and 26-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☒ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of the species set forth in claim 17 in Paper No. 8 is acknowledged. The traversal is on the ground(s) that there is no undue burden of searching has been established by the Examiner. In response, Examiner states that changing the atoms in position X or Y as described in the claim would render divergent hetrocyclic compounds and thus, requires different field of search. For example, when X is O, the claimed compounds would be classified in class 514, subclass 449, but when X or Y is C, the claimed compounds would be classified in class 514, subclass 415. Accordingly, different classifications of the claimed inventions is prima facia indication of undue burden. Regardless, variations in positions X and Y would render patentably distinct compounds possessing various physical and chemical characteristics. Under PCT rule 13.2 they do not share a single general inventive concept. Thus, the election of species is proper.

2. The compound of claim 17 falls within a subgenus of such compounds of claim 1 wherein Z₁ or Z₂ are beno rings, X or Y are R₄-C-R₄, and R₃ or R₄ are substituted or unsubstituted alkyl, and L₁-L₇ contain substituted alkyl. Therefore, the generic claims are searched to the extent that they read on this subgenus and examined accordingly.

Claims 10-12, 14-16, 18-20, 25 are withdrawn as they are not directed to this subgenus or the elected species of claim 17. Claims 1-28 are pending. Claims 1-9, 13, 17, 21-24, 26-28 are under consideration.

Priority

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Japan on September 1998. It is noted, however, that applicant has not filed a certified copy of the Japanese application as required by 35 U.S.C. 119(b).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-9, 13, 21-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Lonsky et al US Patent 5,747,233 or Ohno et al US Patent 4,839,265.

Lonsky et al discloses cyanine dyestuff having a general formula as set forth in col 10, lines 25-65. Lonsky's compositions comprise all features of the generic claim 1, specifically it contains a benzo ring as the instant Z₁ or Z₂, it contains R₄-C-R₄ at position X or Y, and R₃ or R₄ are methyl, and L₁-L₇ contain substituted methyl, it further contains one or more sulfonic acid groups in the molecule (see examples 1-3). Thus, Lonsky anticipates the instant claims.

4. Claims 1-9, 13, 17, 21-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Ohno et al US Patent 4,839,265.

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Similarly, Ohno disclose water soluble cyanine dyes comprising all features of the generic claim 1, specifically it contains a benzo ring as the instant Z_1 or Z_2 , it contains R_4-C-R_4 at position X or Y, and R_3 or R_4 are methyl, and L_1-L_7 contain substituted methyl, it further contains one or more sulfonic acid groups in the molecule (see col 5-6, examples 7; and col 7-8, example 13). Thus, Ohno anticipates the limitations of the instant claims.

5. Claims 1-9, 21-24, 26-28 are rejected under 35 U.S.C. 102(e) as being anticipated by Licha et al US Patent 6,258,340 or Randall et al US Patent 6,114,350.

Licha discloses cyanine dye compositions for diagnostic use comprising same elements as the subgenus instantly claimed. Specifically, Licha's formula I wherein r is 1, L_1 to L_7 is CR and R is alkyl, R_{11} or R_{12} are alkyls, X or Y is $C(CH_3)_2$. (see col 17, lines 55-67, col 18, lines 1-30). Licha et al further disclose methods of using indole compounds for in vivo diagnostic procedures comprising administering to a patient indole compounds as set forth in his claim 1-4 (col 10, lines 30-67; col 17, line 55-65; col 18, lines 30-65). The indole compounds of Licha meet all the limitations of the instant claims as set forth in the instant claim 1, because Licha's compounds, as shown in col 17-18, comprise the same substituents as instantly claimed.

Accordingly, Licha anticipates the instant claims.

Randall discloses methods of diagnostic process using cyanine dyes that anticipates the limitations of the instant claims as set forth above (abstract; col 5, lines 14-40; col 6, lines 6-55; col 8, lines 14-22; table 1, compounds 18-28, specially compounds 24-26). The compounds disclosed by Randall comprise the same

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substituents as the subgenus set forth above and further contain sulfonic acid groups.

Thus, Randall teaches cyanine derivatives that overlap in scope as the instant compounds.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
6. Claims 1-9, 13, 17, 21-24, 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ohno et al US Patent 4,839,265 in view of WO 98/22146 (WO '146) or Licha et al US Patent 6,083,485.

Ohno teaches cyanine dyes see col 5-6, example 7. Ohno does not teach in vivo diagnostic use of the elected species of claim 17.

Both WO '146 (page 32, lines 17-32), and Licha teach the in vivo diagnostic use of various cyanine dyes that fall within the same scope as the instantly claimed compounds.

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Accordingly, it would have been obvious to one of ordinary skill in the art at the time of invention to use the compounds of Ohno for diagnostic purposes, because as by WO '146 and Licha, cyanine dyes can be conventionally formulated and used for in vivo diagnostic use. Accordingly, the ordinary skill in the art would have had a reasonable expectation of observing diagnostic utility when using cyanine dyes of Ohno as suggested by WO '146 and Licha.

Conclusion

7. No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 703-306-5400. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 703-308-1877. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

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December 16, 2002


RUSSELL TRAVERS
PRIMARY EXAMINER
GROUP 1200